



REED TECHNOLOGY

Transforming Data, Delivering Information™
for the Life Sciences Industry

***Reed Tech's eDRL Solution
presented to
HL7 SPL OTC and
Generic Sub-teams***

Mark Bayer, VP, Business Development

Gary Saner, Sr. Manager, Information Solutions-Life Sciences

John Lorenc, Supervisor, Life Sciences Services

November 24, 2008

www.ReedTech.com

+1-215-441-6466

Company Profile

Reed Technology and Information Services Inc.

Philadelphia Headquarters:
7 Walnut Grove Drive
Horsham, PA 19044

Washington Operations:
Alexandria, VA

www.ReedTech.com

+1-215-441-6466



- **47 years of experience; founded in 1961**
- **Over 900 employees**
- **Business unit of LexisNexis and Reed Elsevier**

Reed Tech

- A recognized leader in providing content and life cycle management solutions

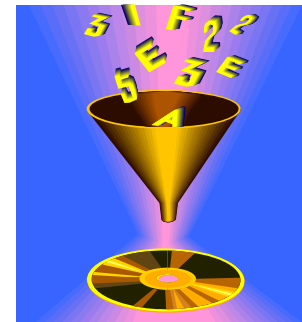
Industries Served

- Life Sciences

- Over 110 manufacturers entrust their labeling conversion and content management to us
- Life cycle management for SPLs
- Prepare, harmonize and convert PIM documents

- Federal Government

Since 1970, the U.S. Patent and Trademark Office has contracted solely with us for publication of patent applications and granted patents, spanning 11 consecutive contract awards



Reed Tech Commitment

We are devoted to the highest standards of quality, service and security

■ Quality

- ISO 9001:2000 certified since 2001
- We keep our knowledge current
 - ◆ HL7 Technical and Process Teams (and various sub-teams)
 - ◆ FDA Regulations and Training Events
 - ◆ Industry Association participation

■ Service

- Turn around times that meet your needs
 - ◆ Standard, Expedited and Emergency delivery options

■ Security

- Electronic Systems, Data, Facility and Staff security
- Encrypted data transfer via secure portal
- Data backup and disaster recovery



Reed Tech SPL Experience

Based on Reed Tech Core Competencies

- XML Creation and Knowledge
 - ◆ 180,000 XML authored pages per week
- Content Composition

2005 Entered the SPL market at inception

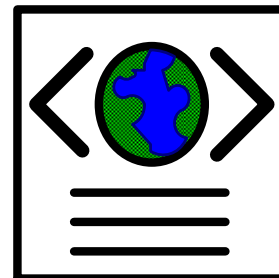
- Human Health Prescription SPL (Oct 2005)

2006 Expanded - Physicians Labeling Rule

- Human Health Prescription SPL-PLR (Jun 2006)

2008 Expanded - eDRL

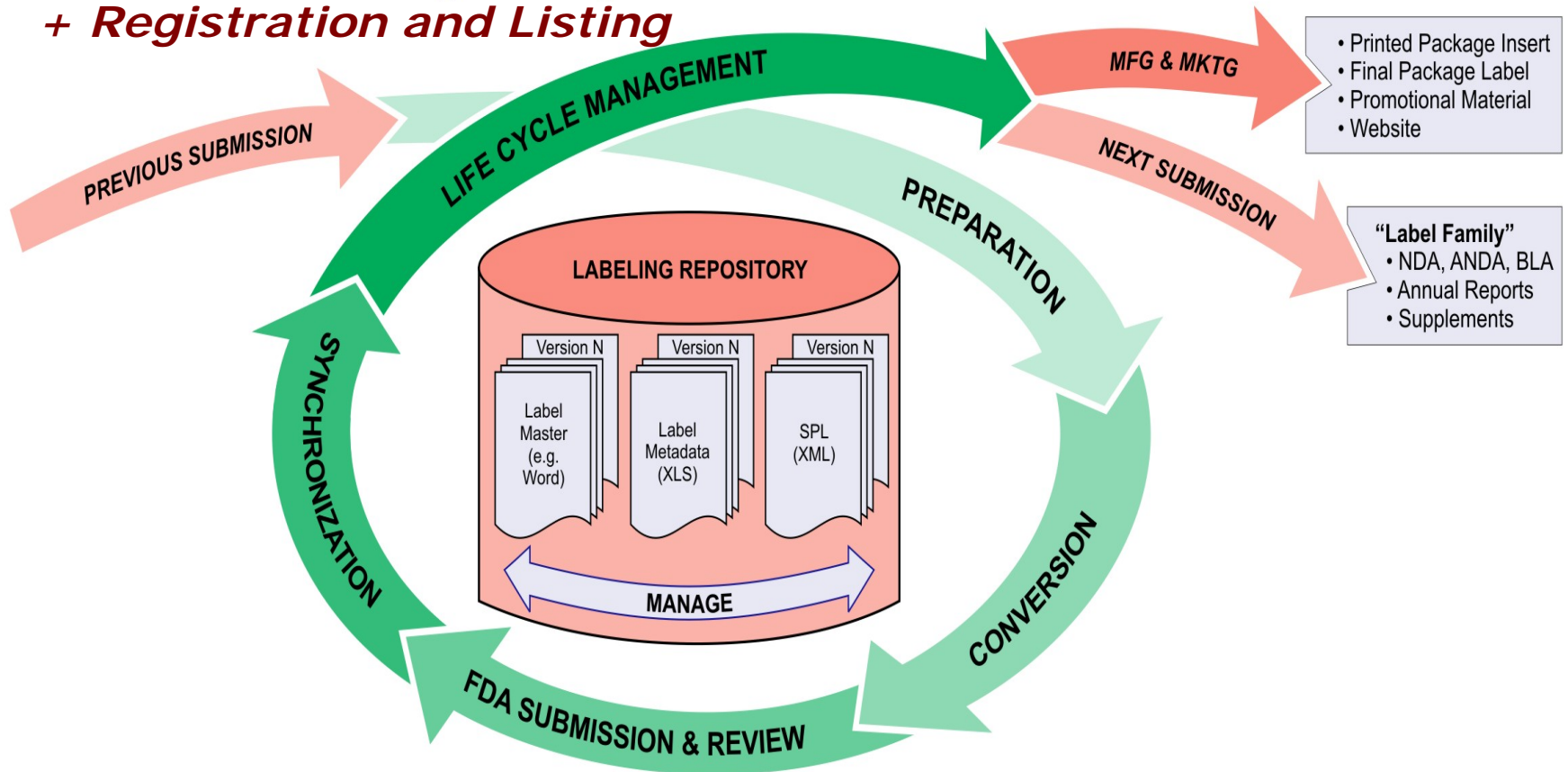
- Human Health (Prescription & OTC), Animal Health, Biologics
- eDRL Pilot Program (SPL-LCR, SPL-REG, SPL-LL in R4 format)



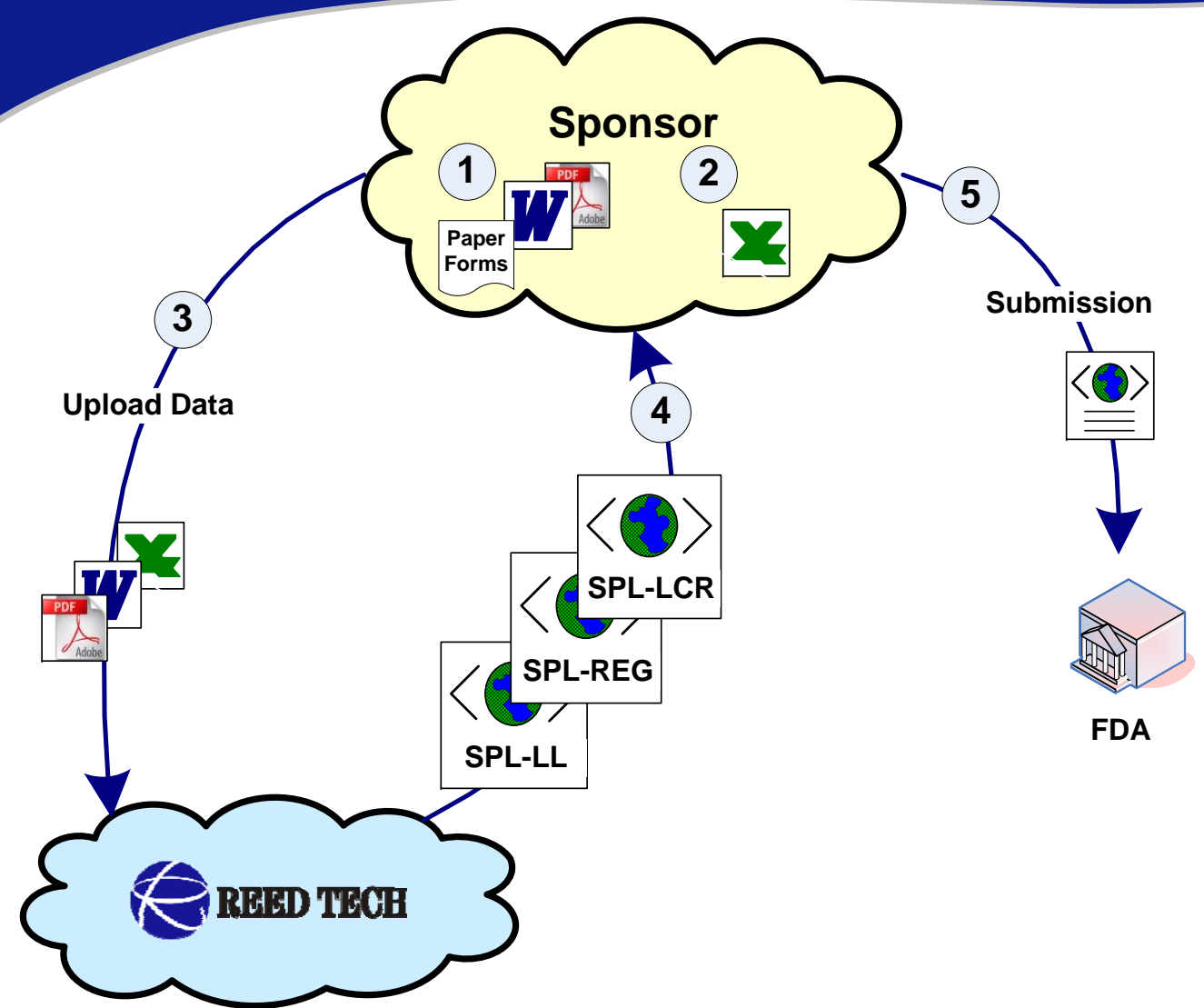
***Over 3,500 SPL conversions delivered to date,
includes all types of SPL submissions***

SPL Life Cycle – Your Challenge

Content of Labeling Life Cycle + *Registration and Listing*



Reed Tech's SPL Solution



FDAAA and SPL

Industry “Jargon”

- **CoL** **Content of Labeling**
- **D-U-N-S** **Data Universal Numbering System
by Dun & Bradstreet**
- **eDRL** **electronic Drug (Establishment) Registration
and (Product) Listing**
- **ESG** **Electronic Submissions Gateway**
- **FDAAA** **FDA Amendments Act**
- **FEI** **FDA Establishment Identifier (Registration Number)**
- **FPI** **Full Prescribing Information**
- **GUID** **Global Unique Identifier**
- **PI** **Package Insert**
- **PDP** **Principal Display Panel**
- **PLR** **Physicians Labeling Rule**
- **SPL** **Structured Product Labeling**
- **XML** **eXtensible Markup Language**

SPL's Expanding Impact

2005 Introduced

- ◆ Human Health Prescription: SPL (Oct 2005)

2006 Expanded – Physicians Labeling Rule

- ◆ Human Health Prescription: SPL-PLR (Jun 2006)

2008 Expanded – CBER and Pilot Program

- ◆ eDRL Pilot Program: SPL R4 (Jul 2008)
- ◆ Biologics/Vaccines CoL: SPL R3 (Oct 2008)

2009 Expanded – eDRL **Mandate**

- ◆ Human Health (Prescription & OTC), Biologics, Animal Health: SPL R4 (Jun 2009)

Current SPL Types

**NLM DailyMed –
4,121 published HHP SPLs
(11/21/08)**

**Reedicon (reedimycin sulfate) Tablet, Film Coated
Reedicon (reedimycin sulfate) Solution
[Reed Tech]**

BOX WARNING

THE BENEFITS OF THERAPY SHOULD BE WEIGHED AGAINST THE RISKS. GROUP, EXPERIENCE IN INDICATION 3 HAS INDICATED THAT THE INCIDENCE OF INDICATION 5 DECREASES CONSIDERABLY IN PROGRESSIVELY OLD PATIENTS. LIVER FUNCTION TESTS SHOULD BE PERFORMED PRIOR TO THERAPY AND AT INTERVALS THEREAFTER, ESPECIALLY DURING THE FIRST SIX MONTHS.

DESCRIPTION

Reedicon sodium is a stable co-ordination compound. Reedicon sodium has the following chemical structure:



SPL-Original

Reedicon sodium occurs as a white powder.

Reedicon sodium extended-release 10 mg and 200 mg tablets are for oral administration. Extended-release tablets contain Reedicon sodium in a once-a-day extended-release formulation. Each 10 mg and 200 mg of hydrochloric.

Inactive Ingredients: Inactive ingredient A, Inactive ingredient B, Inactive ingredient C, Inactive ingredient D, Inactive ingredient E, Inactive ingredient F, Inactive ingredient G, Inactive ingredient H, polyethylene glycol, silicified microcrystalline cellulose, Inactive ingredient K and Inactive ingredient L.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Reedicon Xr safely and effectively. See full prescribing information for Reedicon Xr. Reedicon Xr (reedimycin sulfate) Tablet, Film Coated, Extended Release for Oral use - CTV. Reedicon Xr (reedimycin sulfate) Solution for Intravenous use - CTV. Initial U.S. Approval: 2007

BOXED WARNINGS

All Boxed Warning Highlight text is placed here. All Boxed Warning Highlight text is placed here. All Boxed Warning Highlight text is placed here. All Boxed Warning Highlight text is placed here. All Boxed Warning Highlight text is placed here. All Boxed Warning Highlight text is placed here.

RECENT MAJOR CHANGES

New Drug Application (73)

01/2007

INDICATIONS AND USAGE

Highlight text regarding Indication 1 (1.1).

Highlight text regarding Indication 2 (1.2).

DOSAGE AND ADMINISTRATION

Dosage and administration highlights text is placed here (2).

CONTRAINDICATIONS

- Intestinal disorders such as Ulcerative Colitis, Irritable Bowel Syndrome, or Crohn's Disease (4)
- Severe hepatic impairment (4)
- Anemia (4)
- Chronic Fatigue Syndrome (4)

WARNINGS AND PRECAUTIONS

- Warnings and Precautions highlight text (5.1)
- Warnings and Precautions highlight text (5.2)

ADVERSE REACTIONS

Most common adverse reactions (incidence >2%) are upset stomach, nausea, and vomiting (6)

To report SUSPECTED ADVERSE REACTIONS, contact Reed Tech at 215-441-6466 and www.ReedTech.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

- Drug Interaction 1 (7.1)

USE IN SPECIFIC POPULATIONS

- REEDICON XR should be used with caution in pregnant women (8.1)
- REEDICON XR should be used with caution in nursing mothers (8.3)

CLINICAL PHARMACOLOGY SECTION

Clinical Pharmacology Highlight Text is placed here (12.1)

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved Medication Guide

Revised: 05/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

BOXED WARNING

1 INDICATIONS AND USAGE

- 1.1 Indication 1
- 1.2 Indication 2
- 1.3 NEW INDICATION

2 DOSAGE AND ADMINISTRATION

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Warnings and Precautions - Subsection 1
- 5.2 Warnings and Precautions - Subsection 2
- 5.3 Warnings and Precautions - Subsection 3
- 5.4 Warnings and Precautions - Subsection 4
- 5.5 Warnings and Precautions - Subsection 5

8 ADVERSE REACTIONS

7 DRUG INTERACTIONS

- 7.1 Drug Interaction 1
- 7.2 Drug Interaction 2
- 7.3 New Drug Interaction

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.3 Nursing Mothers

8.4 Pediatric Use

8.5 Geriatric Use

9 DRUG ABUSE AND DEPENDENCE

SPL-PLR

• Highlights

• TOC

• Full Prescribing Information

16.1 Storage

17 PATIENT COUNSELING INFORMATION

17.1 MEDGUIDE

17.2 PATIENT PACKAGE INSERT

* Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

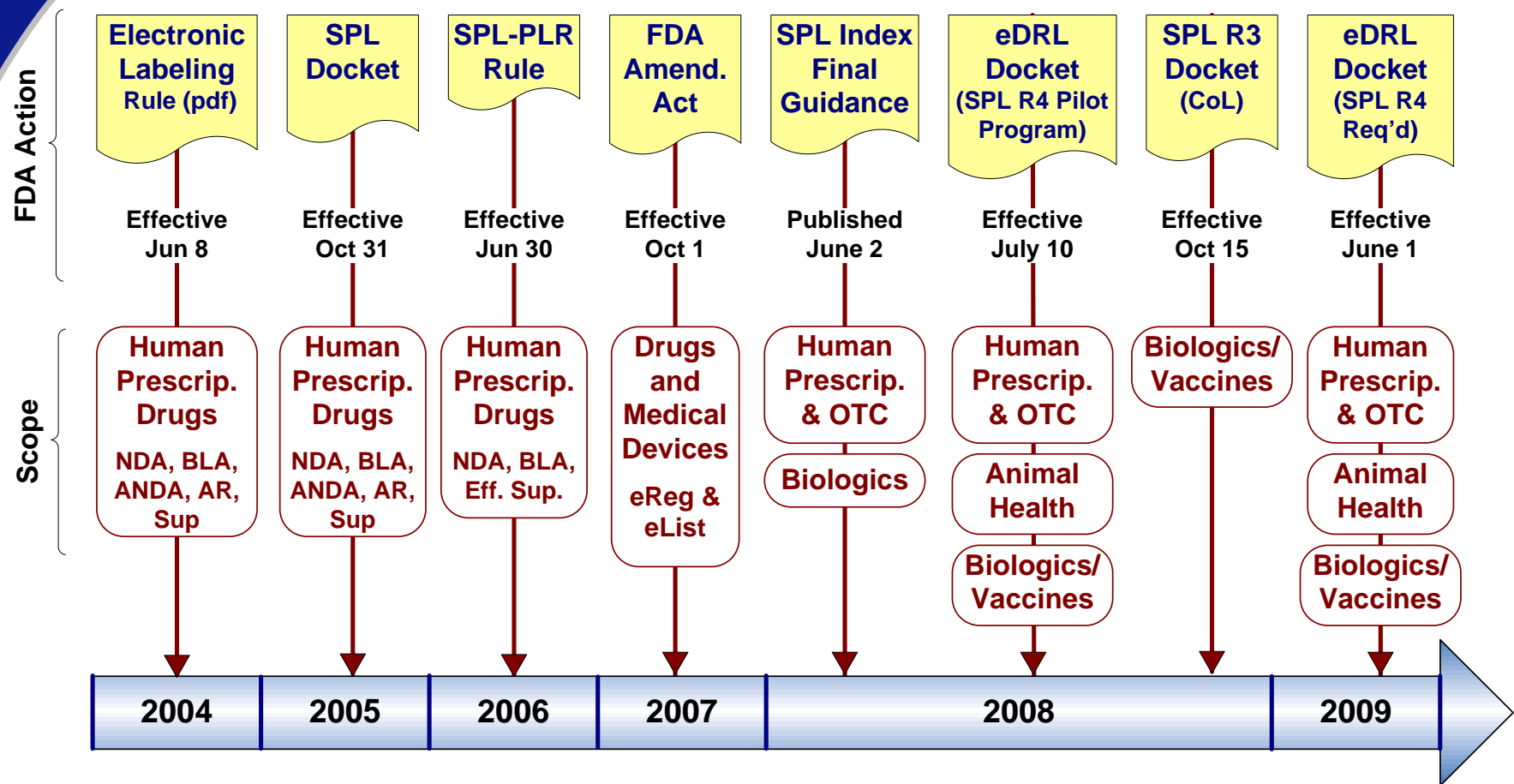
BOXED WARNING

All Boxed Warning text is placed here. All Boxed Warning text is placed here. All Boxed Warning text is placed here. All Boxed Warning text is placed here. All Boxed Warning text is placed here. All Boxed Warning text is placed here.

Today's Focus

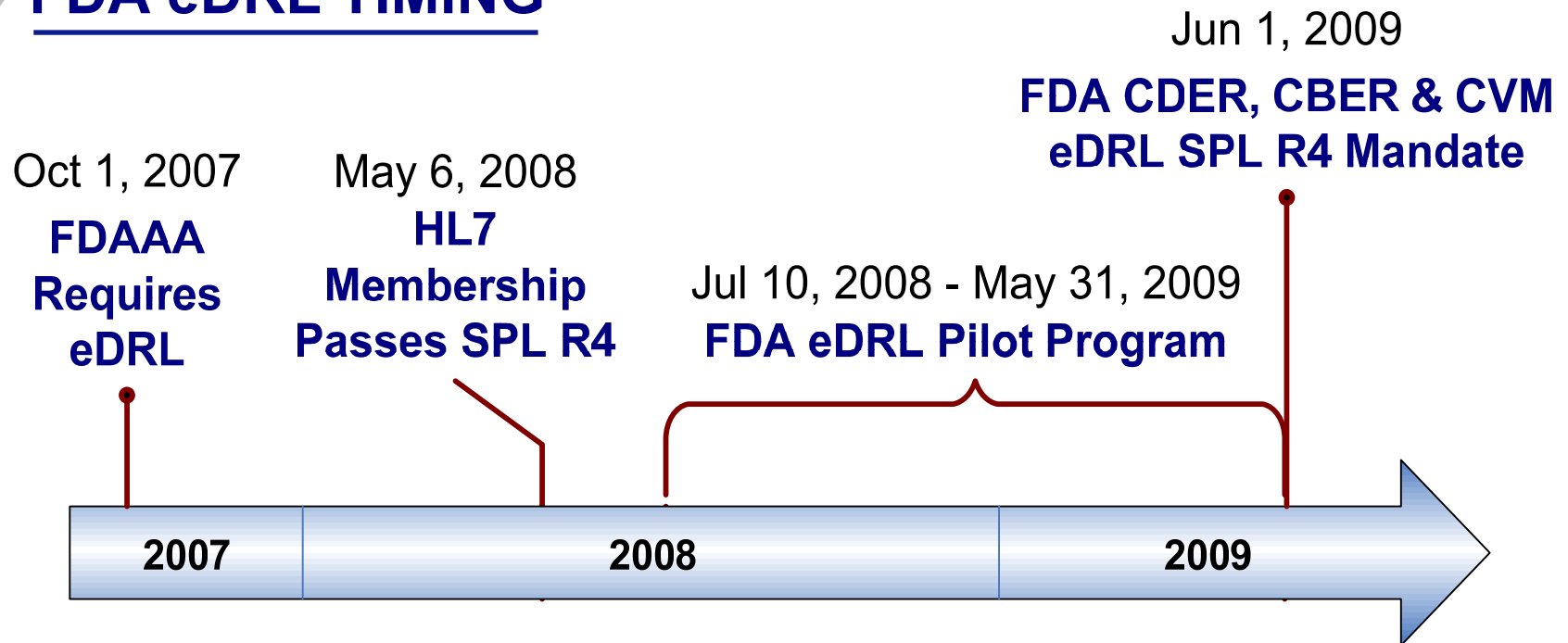


Labeling Milestones



SPL's Expanding Impact (continued)

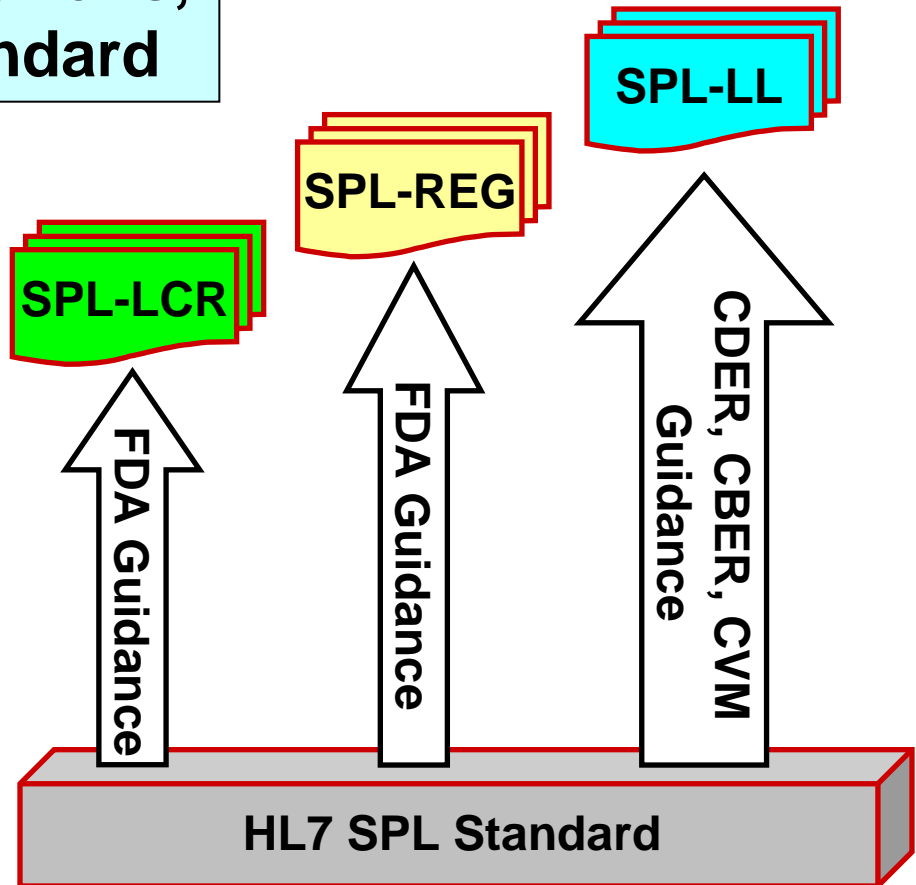
FDA eDRL TIMING



The “New and Expanded” SPL

3 SPL Implementations, using 1 SPL Standard

- SPL-LCR
NDC Labeler Code Request (Form 2656)
- SPL-REG
Establishment Registration (Form 2656)
- SPL-LL
Product Listing and Labeling (Forms 2657, 2658)



SPL-LCR (Labeler Code Request)

■ **Data Collection**

- Data Mapping from Form 2656
- New Data
 - ◆ Labeler D-U-N-S Number
 - ◆ Labeler Contact Person name and information
- Submit an SPL-LCR for each NDC Labeler Code (even if you have one, it populates the new FDA SPL database)

Form 2656 Extracted Data

Form 2656

Approved: OMB No. 0910-0045, Expiration Date: December 31, 2007. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
**REGISTRATION OF DRUG ESTABLISHMENT/
LABELER CODE ASSIGNMENT**
(In accordance with Public Law 92-387)

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than \$1,000, or both. (FD&C Act, Section 303).

SECTION A - SITE INFORMATION

REPORTING FIRM NAME
Reed Tech

SITE ADDRESS (No P.O. Box)
7 Walnut Grove Drive

CITY
Horsham

STATE
PA

ZIP CODE
19044

COUNTRY
USA

SITE MAILING ADDRESS (If different from site address)

CITY

STATE

ZIP CODE

COUNTRY

SITE INTERNET/EMAIL ADDRESS
gsaner@reedtech.com

DOING BUSINESS AS (DBA) NAME OF FIRM (If applicable)

PARENT COMPANY NAME

REASON(S) FOR SUBMISSION

☐ Firm Registration
☐ Registration of Additional Site
☐ Re-Registration
☒ LC Assignment
☐ Name Change

☐ Address Change
☐ Merger/Buyout
☐ Reentry into Business with Same Name
☐ Out of Business

TYPE OF OWNERSHIP

☐ Sole Proprietorship
☐ Partnership
☐ Coop. Assn.
☒ Corporation
☐ Other

PERSON SUBMITTING DATA AND TELEPHONE
Gary Saner (1-215-441-6454)

BUSINESS TYPE

☒ Manufacturer
☐ Repacker
☐ Relabeler
☐ Distributor*
☐ Foreign Country
☐ Analytical Lab
☐ Other

SECTION B - FIRM COMPLIANCE MAILING ADDRESS for Annual Listing Report and/or Firm Correspondence
NUMBER AND STREET AND/OR P.O. BOX AND ATTENTION LINE and/or Internal Mail Code
7 Walnut Grove Drive (Attn: Derek Wirth)

CITY
Horsham

STATE
PA

ZIP CODE
19044

COUNTRY
USA

TELEPHONE NUMBER
(215) 734-2011

COMPLIANCE INTERNET/EMAIL ADDRESS
dwirth@reedtech.com

SECTION C - ADDITIONAL FIRM AND SITE INFORMATION

NAME OF OWNER, PARTNERS OR OFFICERS

TITLE

POSITION

OTHER FIRMS DOING BUSINESS AT THIS SITE

LABELER CODE	FIRM NAME	LABELER CODE	FIRM NAME

SECTION D - SIGNATURE

SIGNATURE OF AUTHORIZING OFFICIAL

TITLE

DATE
10/12/2007

*DISTRIBUTOR'S CERTIFICATION: As a Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656) to the registered manufacturer(s). My signature and phone number are listed below.

RETURN THIS FORM TO:
FOOD AND DRUG ADMINISTRATION
CDER/DRUG REGISTRATION AND LISTING (HFD-337)
5600 FISHERS LANE
ROCKVILLE, MD 20857
INTERNET: DRLS@FDA.HHS.GOV

SIGNATURE OF DISTRIBUTOR

DISTRIBUTOR'S TELEPHONE NUMBER
()

FDA 2656 (8/07) (FRONT)

NOTE: Validation of this form is not to be construed as FDA approval of the establishment or its products. PREVIOUS EDITION IS OBSOLETE.

REPORTING FIRM NAME
Reed Tech

LABELER CODE
1234

Contact?
Name and
Phone

Other
Names

DATE
10/12/2007

SPL-LCR Required Data (Reed Tech Data Collection Form)

From Form 2656

New Data

SPL Id	SPL Submission Type	NDC LABELER CODE REQUEST (51726-8)
	SPL Doc GUID (setId)	36f9a214-e214-42c5-96ce-b6b9136df7aa
	SPL Version GUID (id)	137417de-289e-40ab-aa10-1c54101cccb4
	SPL Version Number	1
	SPL Revision Date	6/20/2008
Labeler	Company Name	Reed Tech
	NDC Labeler Code	1234
	D-U-N-S® Number	884918947
	Contact Name	Gary Saner
	Phone	+1-215-441-6454
	Email	gsaner@reedtech.com
	Street Address	7 Walnut Grove Drive
	City	Horsham
	State	PENNSYLVANIA (PA)
	Postal Code	19044
	Country	United States (USA)

SPL-LCR Rendered View

Reed Tech

Product Information

Product Type

NDC LABELER CODE REQUEST

Labeler - Reed Tech (884918947) NDC Labeler Code: 1234

Contact	Address	Telephone Number	Email Address
Gary Saner	Address: 7 Walnut Grove Drive City, State, Zip: Horsham, PA, 19044 Country: USA	+1-215-441-6454	gsaner@reedtech.com

Revised: 06/2008

Reed Tech

Labeler Code Comparison

	Paper	Electronic
Author	MS Word / Adobe Acrobat	Reed Tech Excel Data Collection Form
Submission	Paper (Form 2656) via postal mail	SPL via ESG
Frequency	Upon change (infrequent)	Initial: prior to SPL-LL On-going: upon change
Noteworthy		D-U-N-S Number, Contact Person

SPL-REG (Establishment Registration)

- **Data Mapping from Form 2656**
- **New Data**
 - Registrant company and contact info
 - Establishment sites, D-U-N-S Number, U.S. Agent, Importer, Contact Person
- **Submit an SPL-REG for each Registrant and its owned Establishments**
- **Non-U.S. Establishments must have one U.S. Agent and at least one Importer**

SPL-REG Extracted Data

Form Approved: OMB No. 0910-0045, Expiration Date: December 31, 2007. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0045, Expiration Date: December 31, 2007. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0045, Expiration Date: December 31, 2007. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

REGISTRATION OF DRUG ESTABLISHMENT/
LABELER CODE ASSIGNMENT
(In accordance with Public Law 92-387)

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than \$1,000, or both. (FD&C Act, Section 303).

SECTION A - SITE INFORMATION

REPORTING FIRM NAME
Reed Tech Manufacturing UK

STATE OF INC.
[]

SITE ADDRESS (No P.O. Box)
13 Strand Avenue

SITE TELEPHONE NUMBER
(20) 7441-6358

CITY
London

STATE
[]

ZIP CODE
WC2N 5JR

COUNTRY
GBR

BUSINESS CATEGORY
☒ HUMAN ☐ VETERINARY

SITE MAILING ADDRESS (If different from site address)
7 Walnut Grove Drive

CITY
Horsham

STATE
PA

ZIP CODE
19044

COUNTRY
USA

SITE INTERNET/EMAIL ADDRESS
gsaner@reedtech.com

DOING BUSINESS AS (DBA) NAME OF FIRM (If applicable)
[]

PARENT COMPANY NAME
Reed Tech

REASON(S) FOR SUBMISSION

☒ Firm Registration ☐ Address Change ☐ Sole Proprietorship ☐ Partnership ☐ Coop. Assn. ☒ Corporation ☐ Other

PERSON SUBMITTING DATA AND TELEPHONE
Gary Saner (1-215-441-6454)

BUSINESS TYPE

☒ Manufacturer ☐ Distributor ☐ Foreign Country ☐ Analytical Lab ☐ Other

SECTION B - FIRM COMPLIANCE MAILING ADDRESS for Annual Listing Report and/or Firm Correspondence

NUMBER AND STREET AND/OR P.O. BOX AND ATTENTION LINE and/or Internal Mail Code
520 Strand Avenue (Attn: John Lorenc)

CITY
London

STATE
[]

ZIP CODE
WC2N 5JR

COUNTRY
GBR

TELEPHONE NUMBER
(20) 7441-6358

COMPLIANCE INTERNET/EMAIL ADDRESS
jlorenc@reedtech.com

SECTION C - ADDITIONAL FIRM AND SITE INFORMATION

NAME OF OWNER, PARTNERS OR OFFICERS

TITLE

POSITION

OTHER FIRMS DOING BUSINESS AT THIS SITE

LABELER CODE

FIRM NAME

LABELER CODE

FIRM NAME

SECTION D - SIGNATURE

SIGNATURE OF AUTHORIZING OFFICIAL

TITLE

DATE
7/23/2008

*DISTRIBUTOR'S CERTIFICATION: As a Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656) to the registered manufacturer(s). My signature and phone number are listed below.

RETURN THIS FORM TO:
FOOD AND DRUG ADMINISTRATION
CDER/DRUG REGISTRATION AND LISTING (HFD-337)
5600 FISHERS LANE
ROCKVILLE, MD 20857
INTERNET: DRLS@FDA.HHS.GOV

SIGNATURE OF DISTRIBUTOR

DISTRIBUTOR'S TELEPHONE NUMBER
()

FDA 2656 (8/07) (FRONT)

NOTE: Validation of this form is not to be construed as FDA approval of the establishment or its products.
PREVIOUS EDITION IS OBSOLETE

Multiple
Forms 2656

Firm Name and
Address

Registration
Number (FEI)
"1234567"

PARENT COMPANY NAME
Reed Tech

REASON(S) FOR SUBMISSION
☒ Firm Registration

Contact Name
and Phone

Business Type
"Manufacturer"

Date
"7/23/2008"

SPL-REG Required Data (Reed Tech Data Collection Form)

SPL Id	SPL Submission Type	ESTABLISHMENT REGISTER
	SPL Doc GUID (setId)	7b3398e5-f3c2-48b5-8bee-6
	SPL Version GUID (id)	78b1e432-bce8-4733-8dc0-0
	SPL Version Number	1
	SPL Revision Date	7/23/2008
Registrant	Company Name	Reed Tech
	D-U-N-S® Number	884918947
	Contact Name	Gary Saner
	Phone	+1-215-441-6454
	Email	gsaner@reedtech.com
	Street Address	7 Walnut Grove Drive
	City	Horsham
	State	PENNSYLVANIA (PA)
	Country	United States (USA)

Establishment	Company Name	Reed Tech Manufacturing UK
	D-U-N-S® Number	230792756
	FEI Number	1234567
	Business Operation	MANUFACTURE (C43360)
	Street Address	13 Strand Avenue
	City	London
	State	None
	Postal Code	WC2N 5JR
	Country	United Kingdom (GBR)
	Contact Name	John Lorenc
U.S. Agent	Phone	+44-20-7441-6358
	Email	jlorenc@reedtech.com
	Street Address	520 Strand Avenue
	City	London
	State	None
	Postal Code	WC2N 5JR
	Country	United Kingdom (GBR)
	Company Name	Reed Tech Associates
	D-U-N-S® Number	234567891
	Business Operation	UNITED STATES AGENT (C73330)
Importer	Contact Phone	+1-215-734-2121
	Contact Email	gmin@reedtech.com
	Company Name	Reed Tech Imports
	D-U-N-S® Number	345678912
	Business Operation	IMPORT (C73599)
	Contact Phone	+1-215-441-6466
	Contact Email	bmcginty@reedtech.com

From Form 2656

New Data

SPL-REG Rendered View

Product Information

Product Type	ESTABLISHMENT REGISTRATION
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Registrant - Reed Tech (884918947)

Contact	Address	Telephone Number	Email Address
Gary Saner	Address: 7 Walnut Grove Drive City, State, Zip: Horsham, PA, 19044 Country: USA	+1-215-441-6454	gsaner@reedtech.com

Establishment

Name	Address	ID/FEI	Operations
Reed Tech Manufacturing UK	Address: 13 Strand Avenue City, State, Zip: London, WC2N 5JR Country: GBR	230792756/123456	MANUFACTURE
Contact	Address	Telephone Number	Email Address
John Lorenc	Address: 520 Strand Avenue City, State, Zip: London, WC2N 5JR Country: GBR	+44-20-7441-6358	jlorenc@reedtech.com
US Agent (ID)	Address	Telephone Number	Email Address
Reed Tech Associates (234567891)		+1-215-734-2121	gmin@reedtech.com
Importer (ID)	Address	Telephone Number	Email Address
Reed Tech Imports (345678912)		+1-215-441-6466	bmcginty@reedtech.com

Establishment Registration Comparison

	Paper	Electronic
Author	MS Word / Adobe Acrobat	Reed Tech Excel Data Collection Form
Submission	Paper (Form 2656) via postal mail	SPL-REG, SPL-NC, SPL-OOB via ESG
Frequency	Annually (<Dec. 31)	Initial: prior to SPL-LL On-going: upon change or annually
Noteworthy		D-U-N-S Number, Contact Person, Establishment Model, (U.S. Agent & Importer)

SPL-LL (Listing and Labeling)

- **Data Mapping from Forms 2657 and 2658**
- **New Data**
 - Manufacturing Information: Labeler, Registrant (optional), Establishment sites, Operations, etc.
 - Product Listing: Active moiety, product size, UNII, etc.
 - Marketing Information: Category, Status, Dates, etc.
- **Negotiation (Word version)**
- **One SPL-LL submitted for each Product (create submission policy with contractors/partners)**
- **Product Listing is the same; Content changes per FDA Center**
 - CDER HHP – CoL
 - CDER OTC – Drug Facts and PDP
 - CDER API – Shipping Label
 - CBER – CoL
 - CVM – Label

SPL-LL Extracted Data

[illegible]

SPL-LL Required Data

(Reed Tech Data Collection Form)

SPL Id	SPL Submission Type	HUMAN PRESCRIPTION DRUG LABEL WITH HIGHLIGHTS (45)
	SPL Doc GUID (setId)	61700eeb-c2db-4772-a317-287f1fa646f4
	SPL Version GUID (id)	12afda09-418c-4ea0-85b8-d23dfafd8368
	SPL Version Number	2
	SPL Revision Date	8/18/2008
Labeler	Company Name	Reed Technology and Information Services Inc.
	D-U-N-S® Number	123456789
Reg.	Company Name	Reed Tech
	Confidentiality	Yes
	D-U-N-S® Number	884918947
Estab.	Company Name	Reed Tech Manufacturing UK
	Confidentiality	Yes
	D-U-N-S® Number	230792756
	Business Operation	MANUFACTURE
Estab.	Company Name	Reed Tech Pharmaceuticals (VA)
	Confidentiality	Yes
	D-U-N-S® Number	949620736
	Business Operation	MANUFACTURE
Product	Product Information	Drug Product # 1
	Proprietary Name	Reedicon
	Proprietary Name Suffix	XR
	Established Name	acetaminophen
	Route of Administration	ORAL (C38288)
	Dosage Form	TABLET, FILM COATED, EXTENDED RELEASE
	DEA Schedule	CIV (C48677)
	Source NDC Product Code	None
Active Ingrd	Active Ingredient Name(s)	acetaminophen
	Active Ingredient UNII code	362O9ITL9D
	Strength Numerator Value	50
	Strength Numerator Unit	MILLIGRAM (C28253)
	Strength Denominator Value	1
	Strength Denominator Unit	Select
	Active Moiety Name	acetaminophen
	Active Moiety UNII code	362O9ITL9D

Inactive Ingrd	Inactive Ingredient Name	magnesium stearate, talc, FD&C blue no. 2
	Inactive Ingredient UNII code	70097M6I30, 7SEV7J4R1U, L06K8R7DQK
	Strength Numerator Value	
	Strength Numerator Unit	Select
	Strength Denominator Value	
Marketing	Strength Denominator Unit	Select
	Category	NDA
	Appl No. or Monograph Citation	NDA123456
	Initial Year of Approval	2008
	Status	Active
Characteristics	Active Date	6/16/2008
	Completed Date	MM/DD/YYYY
	Color	BLUE (C48333)
	Color Description	Sky Blue
	Scoring	2 (equal pieces)
Pkg-Level 1	Shape	OVAL (C48345)
	Shape Description	
	Size	15
	Imprint	REED;50
	Contains	
Pkg-Level 2	Flavor	Grape
	Image	
	Package Type	BOTTLE (C43169)
	Quantity Numerator Value	50
	Quantity Numerator Unit	TABLET (C48542)
Pkg-Level 2	Quantity Denominator Value	1
	Quantity Denominator Unit	Select
	National Drug Code (NDC)	
	Package Type	BOX (C43178)
	Quantity Numerator Value	10
Pkg-Level 2	Quantity Numerator Unit	BOTTLE (C48477)
	Quantity Denominator Value	1
	Quantity Denominator Unit	Select
	National Drug Code (NDC)	1234-5678-05

R3

R4

Form 2657

New Data

SPL-LL Rendered View

Human Health – Prescription

Reedicon

REEDICON - reedimycin sulfate tablet, film coated
 REEDICON - reedimycin sulfate and sodium chloride injection, solution
 Reed Tech

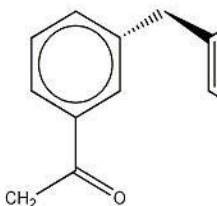
WARNING

Patients taking REEDICON while receiving treatment experience an increase in blood pressure. If you are before beginning treatment with REEDICON [see [WARNINGS](#)].

REEDICON is not to be used by pregnant women or at risk of damage to the fetus [see [PRECAUTIONS](#)].

DESCRIPTION

REEDICON is reedimycin sulfate. The chemical name of reedimycin sulfate is:



reedimycin sulfate

REEDICON (equivalent to 50 mg of reedimycin). Inactive ingredients include magnesium stearate, polyethylene glycol 400, and water.

Each tablet contains reedimycin sulfate (equivalent to 50 mg of reedimycin) and 5 mg of Sodium Chloride. Inactive ingredients include magnesium stearate, iodine, and water.

REEDICON XR - reedimycin sulfate tablet, film coated, extended release
 REEDICON XR - reedimycin sulfate and sodium chloride injection, solution
 Reed Tech

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use REEDICON XR safely and effectively. See full prescribing information for REEDICON XR.

Reedicon XR
 Initial U.S. Approval: 2008

WARNING

See full prescribing information for complete boxed warning.

- REEDICON XR has been known to increase blood pressure in patients taking SSRIs.
- Not for use in pregnant women.

RECENT MAJOR CHANGES

Indications and Usage (1.2)
 Warnings and Precautions (5.3)

INDICATIONS AND USAGE

- REEDICON XR is indicated for
- Chronic pain syndrome (1.1)
 - Generalized aches and pains (1.2)

SPL-PLR (HL, TOC, FPI)

- REEDICON XR SOLUTION SHOULD NEVER BE RECONSTITUTED.

REEDICON

reedimycin sulfate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	1234-6678
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
reedimycin sulfate (reedimycin)	reedimycin sulfate	50 mg

Inactive Ingredients

Ingredient Name	Strength
magnesium stearate	
talc	
FD&C blue no. 2	

Product Characteristics

Color	BLUE (w/ blue), YELLOW	Score	2 pieces
Shape	OVAL (capsule-shaped)	Size	15mm
Flavor	GRAPE (wild grape)	Imprint Code	REED 50
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	1234-6678-08	10 BOTTLE in 1 BOX	contains a BOTTLE
1		50 TABLET in 1 BOTTLE	This package is contained within the BOX (1234-6678-08)



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA123456	01/07/2008	

Labeler - Reed Tech (554915947)

Registrant - Reed Tech (554915947)

Establishment

Name	Address	ID/FEI	Operations
REI Pharmaceuticals (GPR)		554915947	REPACK

Establishment

Name	Address	ID/FEI	Operations
Reed Tech Pharmaceuticals (VA)		554915947	RELABEL

Revised: 06/2008

Reed Tech

SPL-LL Rendered View Biologic / Vaccine

Reedivac

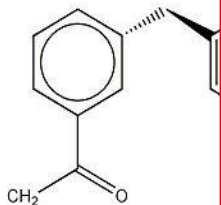
REEDICON - reedimycin sulfate tablet, film coated
REEDICON - reedimycin sulfate and sodium chloride injection, solution
Reed Tech

WARNING

Patients taking REEDICON while receiving treatment experience an increase in blood pressure. If you are before beginning treatment with REEDICON [see [WARNINGS](#)].
REEDICON is not to be used by pregnant women or at risk of damage to the fetus [see [PRECAUTIONS](#)].

DESCRIPTION

REEDICON is reedimycin sulfate. The chemical name of reedimycin sulfate is:



reedimycin sulfate

REEDICON (equivalent to 50 mg of reedimycin). Inactive ingredients include magnesium stearate, talc, and FD&C blue no. 2.
Each tablet contains reedimycin sulfate (equivalent to 50 mg of reedimycin) and 5 mg of Sodium Chloride. Inactive ingredients include magnesium stearate, iodine, and water.

REEDICON XR - reedimycin sulfate tablet, film coated, extended release
REEDICON XR - reedimycin sulfate and sodium chloride injection, solution
Reed Tech

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use REEDICON XR safely and effectively. See full prescribing information for REEDICON XR.

Reedicon XR
Initial U.S. Approval: 2008

WARNING

See full prescribing information for complete boxed warning.

- REEDICON XR has been known to increase blood pressure in patients taking SSRIs.
- Not for use in pregnant women.

RECENT MAJOR CHANGES

Indications and Usage (1.2)
Warnings and Precautions (5.3)

INDICATIONS AND USAGE

- REEDICON XR is indicated for
- Chronic pain syndrome (1.1)
 - Generalized aches and pains (1.2)

SPL-PLR (HL, TOC, FPI)

- REEDICON XR SOLUTION SHOULD NEVER BE RECONSTITUTED.

REEDICON

reedimycin sulfate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	1234-6678
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
reedimycin sulfate (reedimycin)	reedimycin sulfate	50 mg

Inactive Ingredients

Ingredient Name	Strength
magnesium stearate	
talc	
FD&C blue no. 2	

Product Characteristics

Color	BLUE (w/ blue)	Score	2 pieces
Shape	OVAL (capsule-shaped)	Size	15mm
Flavor	GRAPE (wild grape)	Imprint Code	REED 80
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	1234-6678-08	10 BOTTLE in 1 BOX	contains a BOTTLE
1		80 TABLET in 1 BOTTLE	This package is contained within the BOX (1234-6678-08)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA123456	01/07/2008	

Labeler - Reed Tech (884918947)

Registrant - Reed Tech (884918947)

Establishment

Name	Address	ID/FEI	Operations
RE Pharmaceuticals (GPR)		884918947	REPACK

Establishment

Name	Address	ID/FEI	Operations
Reed Tech Pharmaceuticals (VA)		884918947	RE LABEL

Revised: 06/2008

Reed Tech

SPL-LL Rendered View Animal Health

Reedipet

```

1 <?xml version="1.0" encoding="UTF-8"?>
2 <?xml-stylesheet type="text/xsl" href="spl.xsl"?>
3 <document xsi:schemaLocation="urn:hl7-org:v3 PORP_MT050032UV.xsd" xmlns="urn:hl7-org:
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5   <code code="50578-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
PRESCRIPTION ANIMAL DRUG LABEL"/>
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7   <effectiveTime>
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13    <representingOrganization>
14      <id extension="180.0 mg of reedimycin sulfate/mL" />
15      <name>
16      <telecom>
17      <telecom>
18    <assignment>
19    <configuration>
20    <assignment>
21    <id>

```

REEDIPET - reedimycin sulfate solution
Reed Tech Animal Health



180.0 mg of reedimycin sulfate/mL
For Cats only
Not for use in dogs.

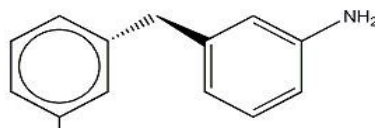
CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Federal law prohibits the extra-label use of this drug in food-producing animals.

DESCRIPTION

Reedipet is a oral solution containing reedimycin sulfate, a synthetic antimicrobial agent. The empirical formula is $C_{10}H_{20}ON$ and the molecular weight is 200.00.

Figure 1. The chemical structure of reedimycin sulfate.



REEDIPET reedimycin sulfate solution			
Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	NDC Product Code (Source)	1234-5678
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
reedimycin sulfate (reedimycin)	reedimycin sulfate	180 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
magnesium oxide	20.3 mg in 1 mL		
phenol	2.6 mg in 1 mL		
monothiolglycerol	6.0 mg in 1 mL		
sodium dioxide			
water			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (wild grape)	Imprint Code	
Contains			
Packaging			
# NDC	Package Description	Multilevel Packaging	
1 1234-5678-10	100 mL in 1 BOTTLE	None	
2 1234-5678-25	250 mL in 1 BOTTLE	None	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA/23456	01/07/2008	
Labeler - Reed Tech Animal Health (884918947)			
Registrant - Reed Tech (884918947)			
Establishment			
Name	Address	ID/FEI	Operations
REI Pharmaceuticals (GBR)		884918947	REPACK
Establishment			
Name	Address	ID/FEI	Operations
Reed Tech Pharmaceuticals (VA)		884918947	RELABEL
Revised: 06/2008			
Reed Tech Animal Health			

SPL-LL Rendered View Human Health – OTC

Reedifed

REEDIFED - reedimycin sodium tablet, film coated, extended release
Reed Tech

Active Ingredient
Reedimycin 100 mg

Uses

- headache
- sneezing
- cough
- dizziness
- confusion
- backache

Warnings

Alcohol warning
reedimycin or other

Do not use

- With any other
- If you have ever

Ask a doctor before

- heart disease
- high blood pressure
- a headache that

Ask a doctor or

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

NDC 1234-5678-24

REEDIFED OTC

Reedimycin 100 mg Caplets

SPL Pain Reliever/Headache Reducer

WARNING: May cause drowsiness

- Fever Reducer
- Body Aches
- Nasal Congestion



Not suitable for households with children contains 24 caplets

PACKAGE LABEL BACK PANEL

Drug Facts (continued)

Warnings

Alcohol warning: If you consume 5 or more alcoholic drinks every day, ask your doctor whether you should take reedimycin or other pain relievers/fever reducers.

Do not use

- With any other product containing reedimycin. Taking more than directed may cause liver damage.
- If you have ever had an allergic reaction to any other SPL pain reliever/fever reducer

Ask a doctor before use if you have

- heart disease
- high blood pressure
- a headache that is different from your usual headaches

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- do not use more than directed
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Drug Facts (continued)

Stop use and ask a doctor if

- new symptoms occur
- your get nervous, dizzy, or sleepless
- SPL pain gets worse or lasts for more than 10

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.

Overdose warning: Taking more than the recommended dose may cause liver damage. In overdose, get medical help or contact a Poison Center right away. Quick medical attention is critical as well as for children even if you do not see any signs or symptoms.

Directions

- do not use more than directed (see overdose warning)
- Adults and children 12 years of age and over: Swallow 2 caplets 4 hours not to exceed caplets in 24 hours
- Children under 12 years of age: Ask a doctor

Other Information

- store at 59° to 77°F in a dry place

REEDIFED

reedimycin sodium tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	1234-5678
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
reedimycin sodium (reedimycin)	reedimycin sodium	100 mg

Inactive Ingredients

Ingredient Name	Strength
hydroxypropylcellulose	
talc	
magnesium stearate	
microcrystalline cellulose	
polyethylene glycol	
pregelatinized starch	
stearic acid	
titanium dioxide	
talc	
FD&C Blue No. 1	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL (capsule-shaped)	Size	18mm
Flavor	GRAPE (wild grape)	Imprint Code	REED
Contains	(alcohol swab)		

Packaging

#	NDC	Package Description	Multilevel Packaging
1	1234-5678-06	1 BLISTER PACK in 1 CARTON	contains a BLISTER PACK
1		24 TABLET in 1 BLISTER PACK	This package is contained within the CARTON (1234-5678-06)



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA123456	01/20/2008	

Labeler - Reed Tech (884918947)

Registrant - Reed Tech (884918947)

Establishment

Name	Address	ID/FEI	Operations
REI Pharmaceuticals (GBR)		054910947	REPACK

Establishment

Name	Address	ID/FEI	Operations
Reed Tech Pharmaceuticals (VA)		054910947	RELABEL

Revised: 06/2008

Reed Tech

SPL-LL Rendered View

Human Health – OTC

Details

Title

Text (.DOC)

"Body" Drug Facts Text

Pkg/Carton Image
(.PDF, other)

"Body" Principal Display Panel Text and Image

Drug Listing Table

Form
2657 +
other
sources

Product Image (future)

Mrktg. and Mfg.
Information Table

REEDIFED - reedimycin sodium tablet, film coated, extended release
Reed Tech

Active Ingredient (in each caplet)
Reedimycin 100 mgPain reliever/Headache reducer


Purposes
Pain reliever/Headache reducer

Uses


- headache
- sneezing
- cough
- dizziness
- confusion
- backache

Warnings
Alcohol warning: If you consume 5 or more alcoholic drinks every day, ask your doctor whether you should take reedimycin or other pain relievers/fever reducers.
Do not use

- With any other product containing reedimycin. Taking more than directed may cause liver damage.
- If you have ever had an allergic reaction to any other SPL pain reliever/fever reducer.

PACKAGE LABEL PRINCIPAL DISPLAY PANEL
NDC 1234-5678-24

REEDIFED OTC
Reedimycin 100 mg Caplets
SPL Pain Reliever/Headache Reducer
WARNING: May cause drowsiness

- Fever Reducer
- Body Aches
- Nasal Congestion


Not suitable for households with children contains 24 caplets

REEDIFED
reedimycin sodium tablet, film coated, extended release

Product Information


Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	1234-5678
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
reedimycin sodium (reedimycin)	reedimycin sodium	100 mg

Inactive Ingredients

Ingredient Name	Strength
hydroxyethylcellulose	
talc	
magnesium stearate	
microcrystalline cellulose	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	ND123456	01/01/2008	

Labeler - Reed Tech (884918947)

Registrant - Reed Tech (884918947)

Establishment

Name	Address	ID/FEI	Operations
REI Pharmaceuticals (USA)		884918947	REPACK

Establishment

Name	Address	ID/FEI	Operations
Reed Tech Pharmaceuticals (VA)		884918947	RELABEL

Revised: 06/2008

Reed Tech

Product Listing Comparison

	Paper	Electronic
Author	MS Word / Adobe Acrobat	Reed Tech Excel Data Collection Form
Submission	Paper (Form 2657/2658) via postal mail	SPL-LL via ESG
Frequency	Upon change or semi-annually (June, Dec.) if change	Initial: for public awareness On-going: upon change or semi-annually if change
Noteworthy		Labeler & Establishment, Mrktg/Mfg Info, SRS UNII

SPL Life Cycle – Your Challenge

- **Content Owner Responsibilities**
 - Monitor labeler code, establishment and listing changes
 - Update SPL as appropriate
 - Resubmit SPL
- **SPL Version Control**
 - Version number
 - GUIDs
 - Dates
 - Etc.
- **Manage Multiple Versions**
 - Internal corporate version (website, collateral)
 - FDA “Center Review” version for approval
 - ◆ Parallel submissions
 - NLM DailyMed and Drugs@FDA public versions

SPL Life Cycle – Your Challenge (continued)

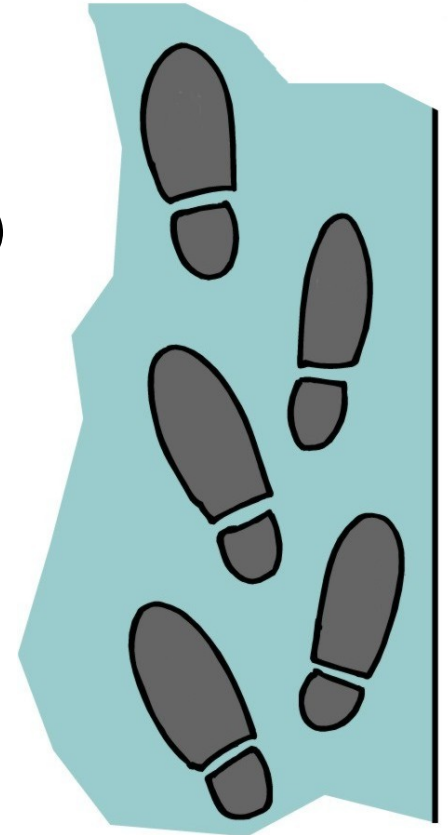
NDC Product Code				NDC Package Code			SPL "Grouping" (TBD)				
Code	Drug Name	Dosage Form	Strength	Code	Pkg	Count	A	B*	C	D	
1111	MyDrug	Tablet	25 MG	01	Bottle	10	#1	#1	#1	#1	
				02	Bottle	50	#2				
				03	Bottle	100	#3				
2222	MyDrug	Tablet	75 MG	04	Bottle	10	#4	#2			
				05	Bottle	50	#5				
3333	MyDrug	GelCap	75 MG	06	Blister	10	#6	#3	#2		
				07	Blister	50	#7				

* Matches Form 2657

Reed Tech's SPL Solution

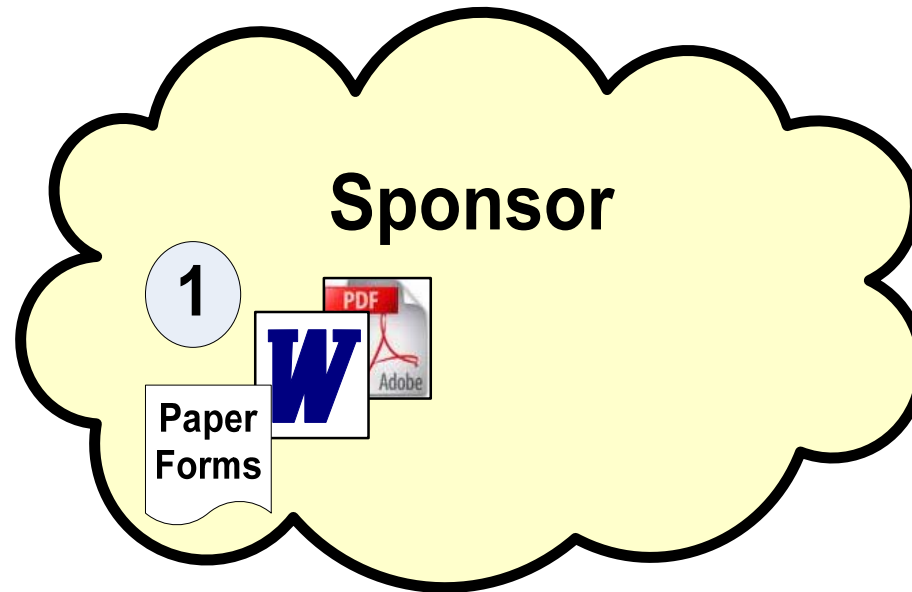
Reed Tech's SPL Solution – 5 Easy Steps

- 1. Collect Source Content**
(Forms 2656, 2657, 2658, and Labeling)
- 2. Populate Data Collection Forms**
(We do it or you do it)
- 3. Upload Data to Secure Portal**
- 4. Receive and Confirm SPL**
- 5. Submit SPL**



Reed Tech's SPL Solution

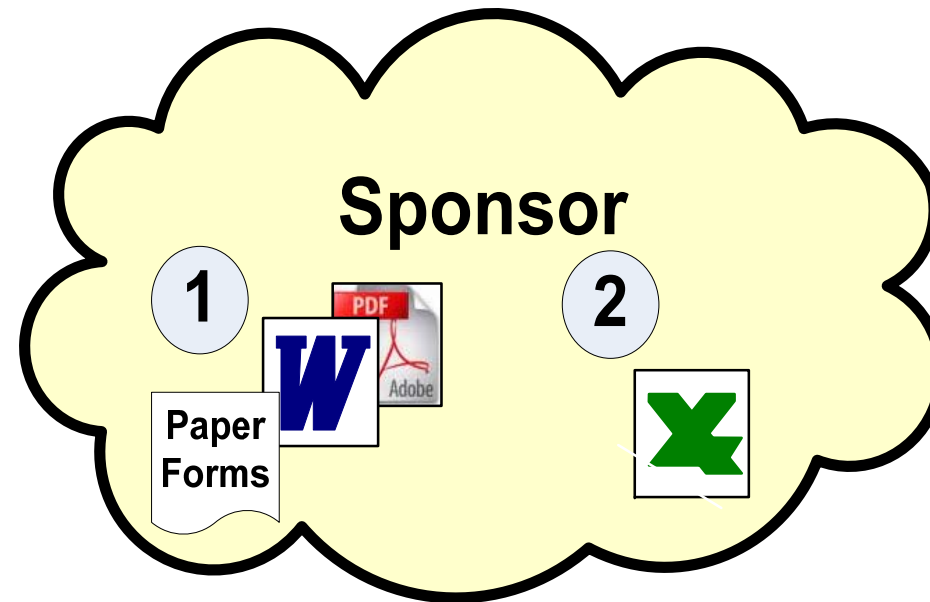
1. Collect Source Content



***Reed Tech Support –
Always Available***

Reed Tech's SPL Solution

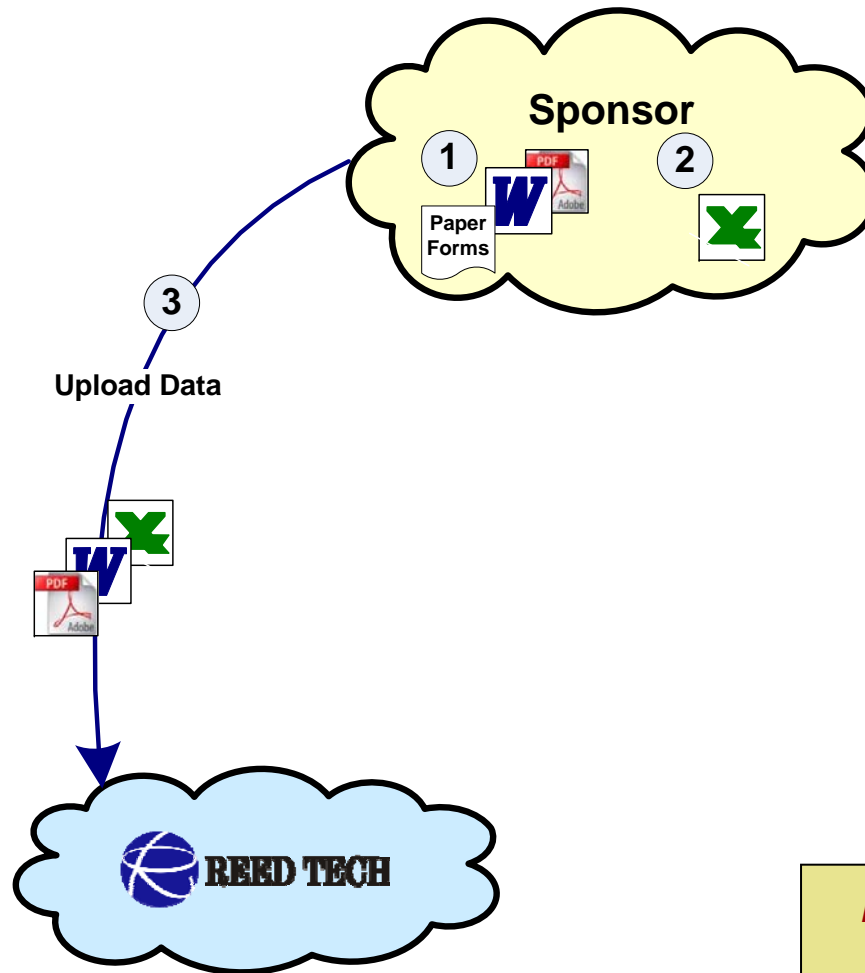
2. Populate Data Collection Forms



***Reed Tech Support –
Always Available***

Reed Tech's SPL Solution

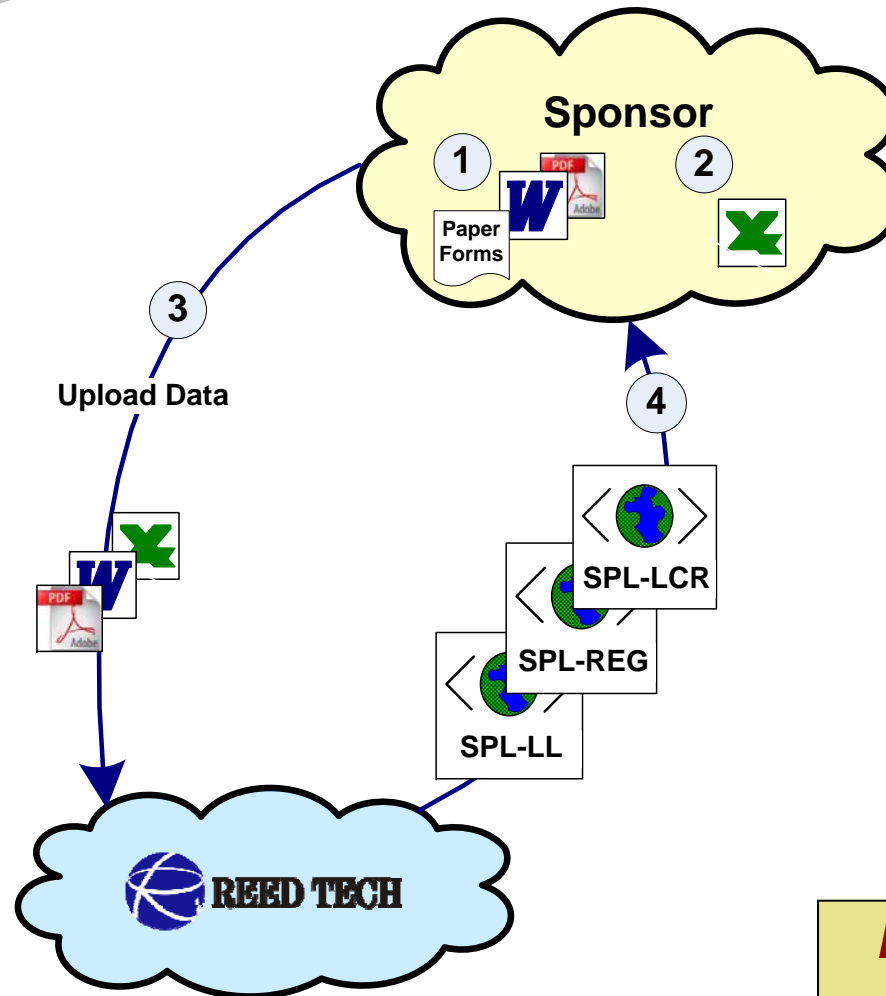
3. Upload Data to Secure Portal



**Reed Tech Support –
Always Available**

Reed Tech's SPL Solution

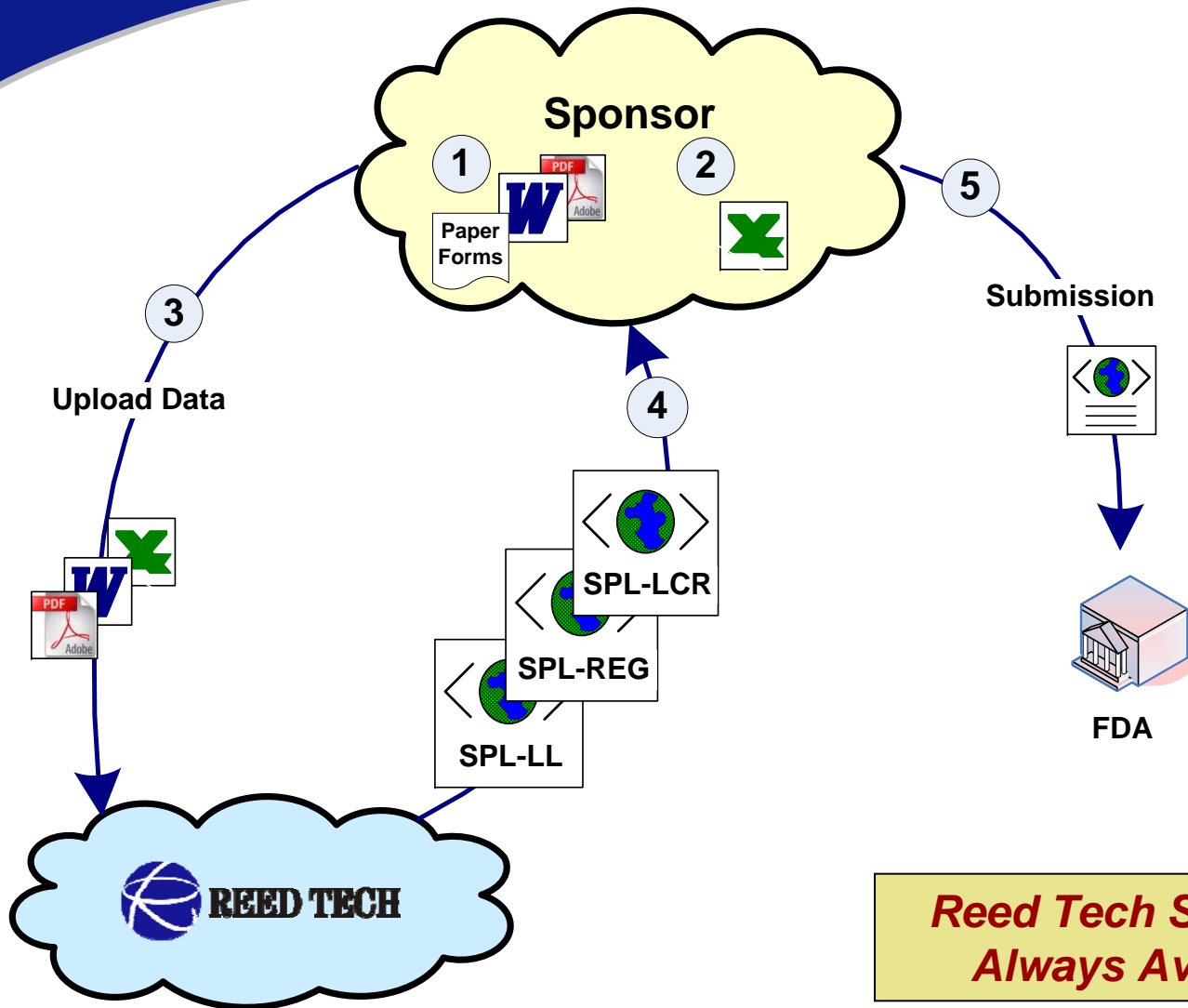
4. Receive and Confirm SPL



**Reed Tech Support –
Always Available**

Reed Tech's SPL Solution

5. Submit SPL



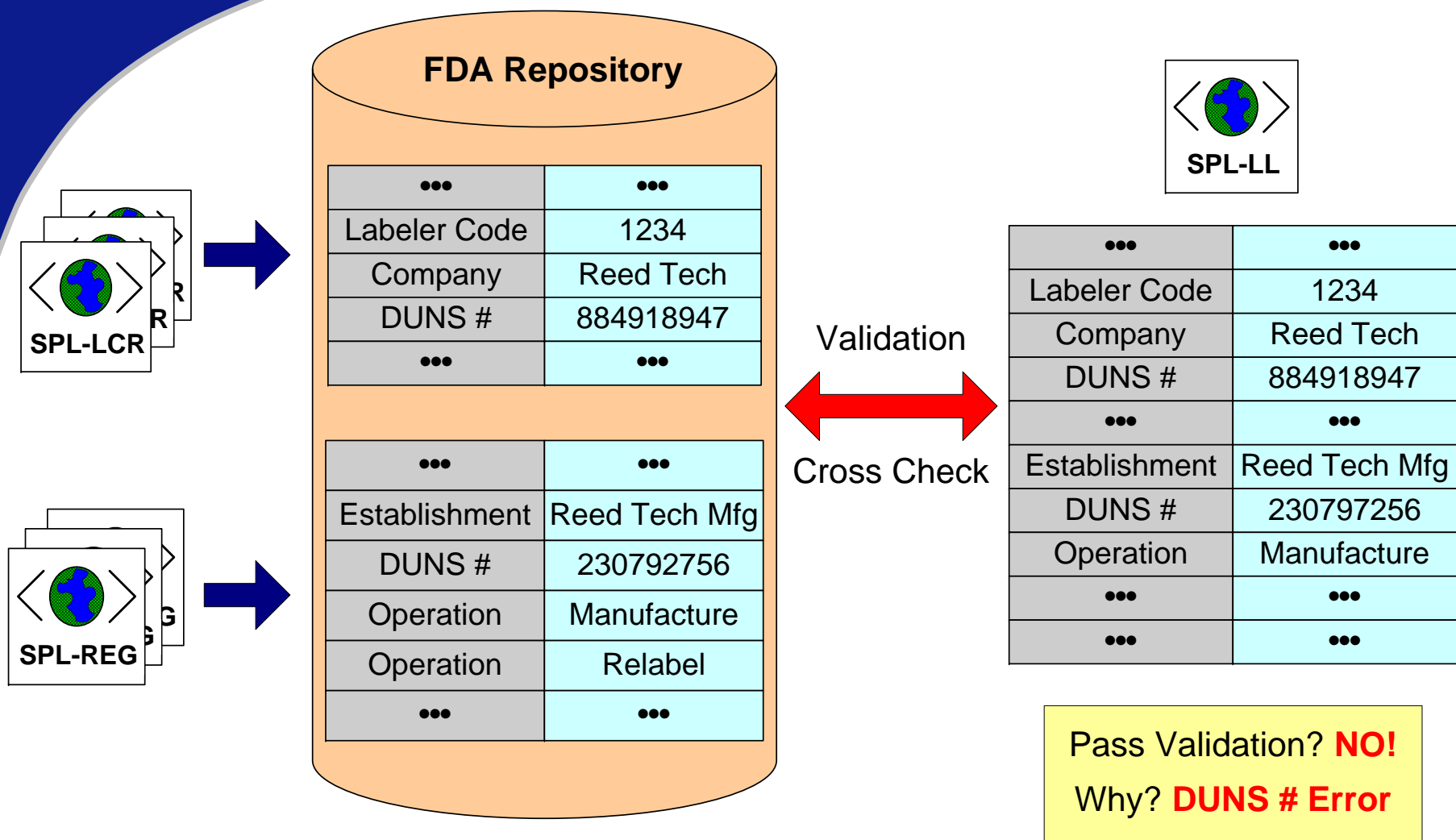
**Reed Tech Support –
Always Available**

Reed Tech Solution Features

- Sponsor only needs MS Internet Explorer to transfer data and view SPL
- Service model easily supports one or multiple client sites
- **Reed Tech will:**
 - Provide easy-to-use data collection forms
 - Accurately transfer Labeler information into SPL XML structure, e.g. GUIDs, effectiveTimes
 - Check presence/format of data values, e.g. D-U-N-S number, phone, email
 - Control SPL Versions and Life Cycle Management (version number, GUIDS, effectiveTime, etc.)
 - Convert SPL R3 to R4 format
 - **Validation Cross Check** SPL-NDC / SPL-REG / SPL-LL

Reed Tech Solution Features (continued)

Importance of Validation Cross Check



Reed Tech Solution Features (continued)

Reed Tech will:

- Perform **rigorous validation** (automated and human expertise)
 - Terminology
 - FDA Tier 1 Schema/Parsing
 - FDA Tier 2 Business Rules
 - Reed Tech Value Added Business Rules
 - Customer Specific Business Rules
- Apply FDA Regulation and Terminology updates within 1 day of FDA posting
- Provide Ongoing **Life Cycle Management**
- Provide SPL submission via **ESG**

- *Reed Tech is now creating SPL Revision 4 documents for the FDA eDRL Pilot Program*
- *All SPLs submitted to date have successfully passed FDA validation*
- *You benefit from Reed Tech's SPL Subject Matter Expertise, Technology, and Delivery*

Outsourced Solution vs. Purchased Software

■ Outsourced Solution:

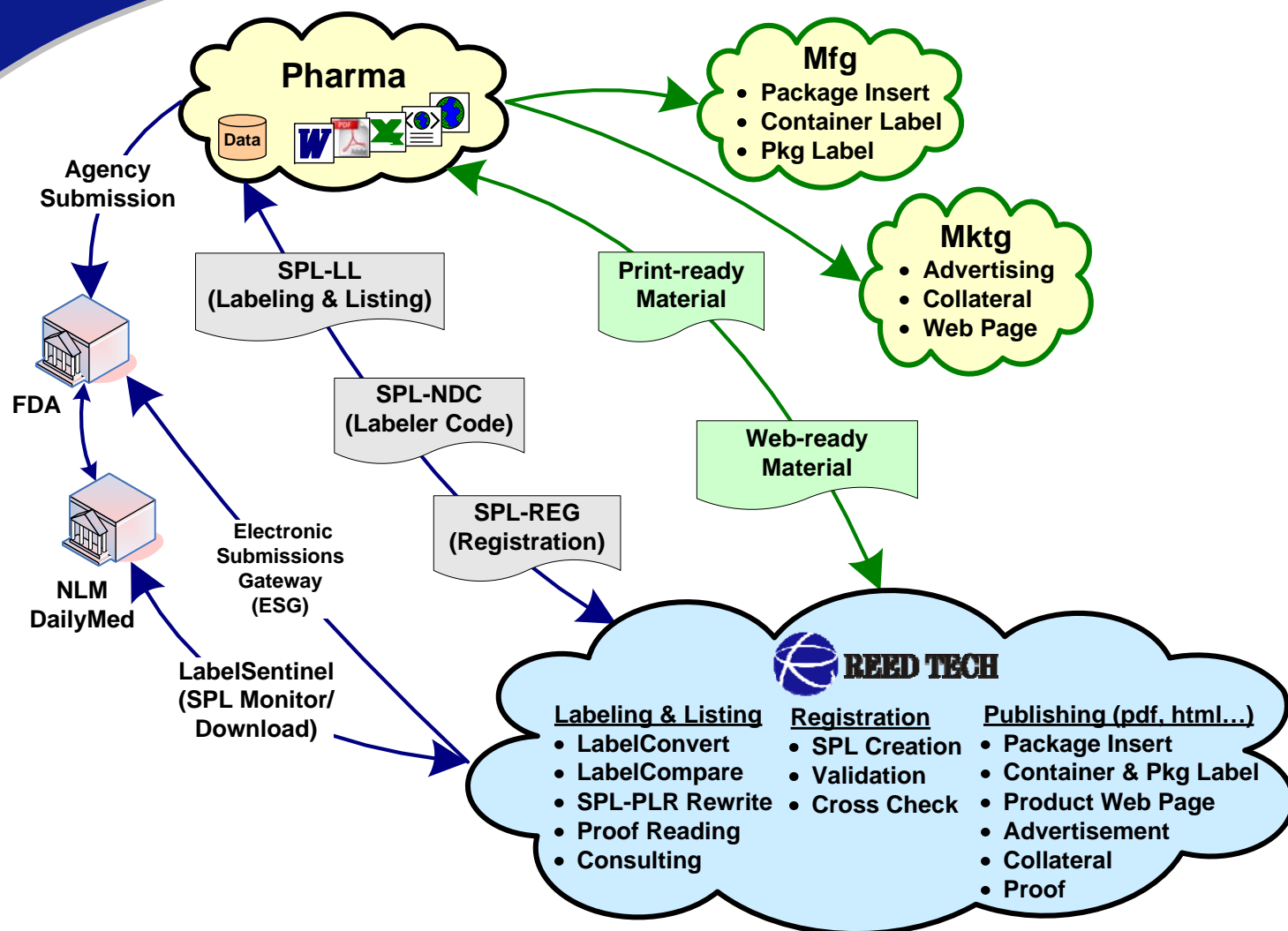
- Easiest for your Regulatory and IT staff
- Leverages Reed Tech's Subject Matter Expertise
- Highly **cost-effective**
- Secure, accurate, and **on-time**
- Reacts immediately to FDA guidance changes

■ Purchased Software:

- High purchase/maintenance costs
- Installation/validation time and costs
- Regulatory and IT Training necessary
- Potential delays of version updates

***Beyond the FDA mandate,
what value does your
SPL XML provide?***

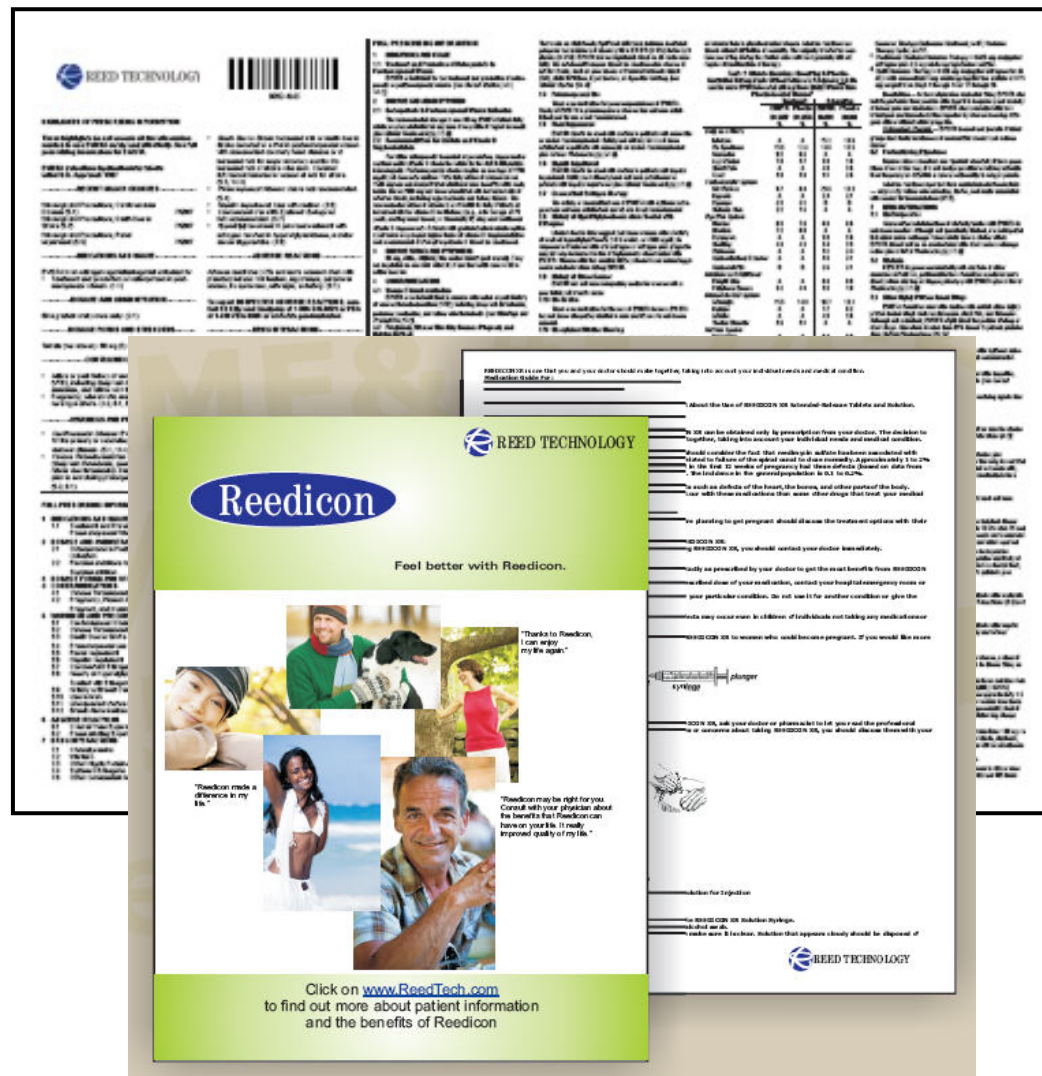
XML Reuse for Downstream Manufacturing and Marketing Publishing



SPL Content Repurposed

- **Print-ready formatted output**
 - e.g. PDF, Adobe InDesign

- **Web-ready**
 - e.g. HTML, XHTML



Reed Tech's SPL Solution – What Sets Us Apart?

- **Extensive Regulatory Knowledge**
 - FDA Rules, Guidance, and Pilot Program
 - Changes implemented within one day
- **Associations**
 - HL7, DIA, RAPS
- **Real World SPL Experience**
 - Over 110 Customers; over 3,500 SPLs
- **Industry Leading Customer Support**
 - “John, Grace, Gary, and team”
- **Strong Technology**
 - XML, Validation, GMP

Quality, Timely, and Cost Effective

Questions and Answers



Appendix

FDA SPL Reference Sites

■ FDA SPL Website

- SPL-Original, SPL-PLR, and SPL R4 information (Guidance for Industry, Implementation Guides, Schema & Stylesheet, Resource Links, etc.)

<http://www.fda.gov/oc/datacouncil/spl.html>

■ FDA SPL-PLR Reference Website

Comprehensive collection of SPL-PLR reference information (Press Release, Summary, Q&A, CFR Rule, Guidance for Industry, Examples, etc.)

<http://www.fda.gov/cder/regulatory/physLabel/default.htm>

■ FDA CONTACTS

- Help: spl@fda.hhs.gov
- New Drug Applications: Lonnie Smith, +1-301-594-0011
- Abbreviated New Drug Applications: Koung Lee, +1-301-827-7336

SPL Reference Sites

- **NLM DailyMed Website**
View or download published SPLs
<http://dailymed.nlm.nih.gov/dailymed/about.cfm>
- **FDA Electronic Submissions Gateway Website**
Setup an ESG account
<http://www.fda.gov/esg/>
- **FDA Data Council Home page**
Sign up for email updates
<http://www.fda.gov/oc/datacouncil/>
- **Dun & Bradstreet Website**
View or create your DUNS number
<http://www.dnb.com/>

Reed Tech Contact Information



REED TECHNOLOGY AND INFORMATION SERVICES

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